**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSSTES**

MARY SZARKOWSKI,

*Plaintiff,*

v.

TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS U.S.A., INC., (f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.); TAKEDA PHARMACEUTICAL COMPANY LIMITED; TAKEDA CALIFORNIA, INC. (f/k/a TAKEDA SAN DIEGO, INC.,) and ELI LILLY AND COMPANY,

*Defendants.*

C.A. No.:

**JURY TRIAL DEMANDED**

# COMPLAINT

Plaintiff MARY SZARKOWSKI by and through her attorneys NAPOLI SHKOLNIK, PLLC, bring this action for personal injuries suffered as a proximate result of PLAINTIFF being prescribed and ingesting the defective and unreasonably dangerous drug Actos™ (pioglitazone), a prescription medication used to improve blood sugar (glucose) control in adults with Type II diabetes. Actos, at all times relevant hereto, was manufactured designed, tested, packaged, labeled, marketed, advertised, distributed, prescribed, and sold by Defendants identified herein.

## I. PARTIES

1. At all times relevant hereto, Plaintiff MARY SZARKOWSKI was a resident and citizen of the State of Massachusetts.

1. Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware Corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

2. Takeda America is a wholly owned subsidiary of Takeda U.S.A.

3. Takeda Pharmaceuticals U.S.A., Inc. f/k/a Takeda North America, Inc. ("Takeda U.S.A.") is a Delaware corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

4. Takeda U.S.A. is a wholly owned subsidiary of Takeda Limited.

5. Takeda Pharmaceutical Company Limited ("Takeda Limited") is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chrome, Chuo-ku, Osaka, 540-8645, Japan.

6. Takeda Limited is the parent company of Takeda U.S.A., and Takeda America is a wholly owned subsidiary of Takeda U.S.A.

7. Takeda America, Takeda U.S.A., and Takeda Limited (collectively, the "Takeda Defendants") have conducted business and derived substantial revenue from Massachusetts, including marketing, disseminating and selling their Actos product in Massachusetts, to patients like the decedent.

8. Takeda America, Takeda U.S.A., and Takeda Limited have derived substantial revenue from goods and products disseminated and used in the State of Massachusetts, including the Actos prescription drug product.

9. Takeda America, Takeda U.S.A., and Takeda Limited purposefully placed the Actos prescription drug product into the stream of commerce and should have reasonably expected their acts to have consequences within the State of Massachusetts.

10. Takeda America, Takeda U.S.A., and Takeda Limited continuously conducted business in the State of Massachusetts at all times relevant herein.

11. The Takeda Defendants promoted, designed, manufactured, and sold the Actos™ prescription drug product in the State of Massachusetts. Plaintiff's decedent was prescribed the Actos™ prescription drug in the State of Massachusetts, used the Actos drug in Massachusetts, was treated for his bladder cancer in Massachusetts

12. The Takeda defendants purposefully availed themselves of the benefits of conducting business in the State of Massachusetts by designing the Actos product and marketing, promoting, and selling the Actos™ prescription drug to physicians such as Plaintiff's prescribing physician and individuals like the Plaintiff.

13. Takeda America, Takeda U.S.A., and Takeda Limited expected or should have expected their acts to have consequences within the State of Massachusetts and derived substantial revenue from interstate commerce.

14. Defendant, Takeda California, Inc., (f/k/a Takeda San Diego, Inc.) is a California corporation, having a principal place of business at 10410 Science Center Drive, San Diego, CA 92121. As part of its business, Takeda California Inc. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and Pioglitazone Hydrochloride.

15. Takeda California, Inc. is a wholly-owned subsidiary of Takeda North America.

16. Takeda California, Inc. has transacted and conducted business within the State of Massachusetts.

17. Takeda California, Inc. has derived substantial revenue from goods and products used in the State of Massachusetts. Takeda California, Inc. expected or should have expected their acts to have consequences within the State of Massachusetts, and derived substantial revenue from interstate commerce.

18. Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

19. Lilly (collectively the "Eli Lilly Defendants") have transacted and conducted business within the State of Massachusetts, including marketing, promoting, and selling their Actos product in Massachusetts, and to patients like the Plaintiff's decedent and his prescribing physician.

20. Lilly has derived substantial revenue from goods and products disseminated and used in the State of Massachusetts.

21. Lilly purposefully placed the Actos prescription drug product into the stream of commerce and should have reasonably expected their acts to have consequences within the State of Massachusetts.

22. The Lilly Defendants promoted, designed, manufactured, and sold the Actos™ prescription drug product in the State of Massachusetts, including to Plaintiff and Plaintiff's prescribing physician.

23. Lilly expected or should have expected their acts to have consequences within the State of Massachusetts, and derived substantial revenue from interstate commerce.

## II. JURISDICTION AND VENUE

24. This Court has personal jurisdiction over the Defendants based on Diversity of Citizenship pursuant to 28 U.S.C. Section § 1332(a)(1), and the amount in controversy is in excess of the jurisdictional limit of $75,000.

25. At all times relevant hereto, Plaintiff MARY SZARKOWSKI was a resident of Middlesex County, Massachusetts.

26. Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware Corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

27. Takeda America is a wholly owned subsidiary of Takeda U.S.A.

28. Takeda Pharmaceuticals U.S.A., Inc. f/k/a Takeda North America, Inc. ("Takeda U.S.A.") is a Delaware corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

29. Takeda U.S.A. is a wholly owned subsidiary of Takeda Limited.

30. Takeda Pharmaceutical Company Limited ("Takeda Limited") is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chrome, Chuo-ku, Osaka, 540-8645, Japan.

31. Takeda Limited is the parent company of Takeda U.S.A., and Takeda America is a wholly owned subsidiary of Takeda U.S.A.

32. Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

33. Takeda USA, Takeda America, Takeda Limited, and Lilly have all derived substantial revenue from goods and products disseminated and used in the State of Washington

through their design, manufacture, marketing, selling, and distributing of the prescription drug, Actos™.

34. The Takeda defendants purposefully availed themselves of the benefits of conducting business in the State of Washington by designing the Actos product and marketing, promoting, and selling the Actos™ prescription drug to physicians such as Plaintiff's prescribing physician, and plaintiffs themselves.

35. Takeda America, Takeda U.S.A., Takeda Limited and Eli Lilly expected or should have expected their acts to have consequences within the State of Washington and derived substantial revenue from interstate commerce.

36. Jurisdiction over the Defendants is present here as Plaintiffs' claims arise out of or relate to at least one of the Defendant's contacts with the forum, the Defendant purposefully availed itself of the forum, and exercising jurisdiction over the foreign Defendants does not violate traditional notions of fair play and substantial justice.

37. Venue is proper pursuant to 28 U.S.C. 51391 because the claims made in this case, specifically, Plaintiff's prescription and use of the Actos product, her bladder cancer diagnosis, and the injuries stemming therefrom.

## III. FACTUAL BACKGROUND

38. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold Actos™, for the treatment of Type II diabetes mellitus.

39. According to the American Diabetes Association, Type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or does not efficiently use the insulin that it does produce. Type I diabetes occurs when

the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

40. Actos™ was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat Type II diabetes.

41. Actos was jointly launched by Takeda North America and Lilly in 1999.

42. Actos™ is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZDs").

43. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda North America and Lilly to promote and market Actos.

44. Takeda Limited described this partnership as "a great success" and "mutually beneficial to both companies."

45. Actos™ exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos™ is only used to treat Type II diabetes and should not be used to treat Type I diabetes.

46. Actos™ is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

47. As a result of the defective nature of Actos™, persons who were prescribed and ingested Actos™ for more than twelve months, including Plaintiff, were at increased risk for developing bladder cancer, have suffered and may continue to suffer from bladder cancer.

48. As a result of the defective nature of Actos™, persons who were prescribed and ingested Actos™ for more than twelve months, including Plaintiff, developed bladder cancer, have suffered and may continue to suffer from bladder cancer.

49. Defendants concealed their knowledge that Actos™ can cause bladder cancer from Plaintiff, other consumers, and the medical community.

50. Specifically, Defendants did not adequately inform consumers and the prescribing medical community about the risks of bladder cancer associated with the use of Actos™ for more than twelve months.

51. As a result of Defendants' actions and inactions, Plaintiff was injured due to ingestion of Actos™, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

52. Prior to Actos™ being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos™ that produced blood drug levels equivalent to those resulting from a clinical dose.

53. In 2005, the results of the PROactive (PROspective PioglitAzone Clinical Trial In MacroVascular Events) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using Actos™. Dormandy J.A., et al. Secondary Prevention of Macrovascular Events in Patients with Type II Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial, Lancet, 266:1279-1286 (2005) (the "Dormandy paper").

54. The PROactive study was looking at cardiovascular events and outcomes.

55. During the course of monitoring the study, the researchers and Defendants became aware that there was a statistically significant demonstrated higher percentage of bladder cancer cases in patients receiving Actos™ versus comparators.

56. Neither during the study, nor in the actual final Dormandy paper, did the researchers or the Defendants publish these statistically significant increases of bladder cancer.

57. This information was not included in the published Dormandy paper.

58. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of cancer in users of Actos™ to prevent any chances of its products' registrations being delayed or rejected by FDA.

59. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving Actos™ versus comparators.

60. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos™ and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos™ use, reaching statistical significance after 24 months.

61. Despite FDA finding that Actos™ is linked to a statistically significant increase in the risk for developing bladder cancer, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from Actos™.

62. In early 2011, the American Diabetes Association published Piccinni, et al. Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting, Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. This study looked at adverse events reports made to the FDA between 2004 and 2009. The

conclusion of that study was that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies."

63. On June 9, 2011, the European Medicines Agency announced that it had been informed by the French Medicines Agency of its decision to suspend the use of pioglitazone containing medicines (Actos™, Competact) in France while awaiting the outcome of the ongoing European review.

64. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan, which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos™ for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

65. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos™ after Germany's Federal Institute for Drugs and Medical Devices. ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

66. On June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication Actos™ (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." The FDA ordered information about this risk to be added to the Warnings and Precautions section of the label for pioglitazone-containing medicines.

67. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposure to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with Actos™ for longer than 12

months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

68. On July 12, 2011, Takeda Limited issued a recall on Actos™ in France.

69. Following the recall in France, Takeda Limited refused to issue a recall of Actos™ in the United States thereby continuing to subject American citizens to the significant risk of developing bladder cancer while ensuring the users in France and Germany were no longer subject to this risk.

70. As the manufacturers and distributors of Actos™, Defendants knew or should have known that Actos™ use for longer than twelve months was associated with bladder cancer.

71. With the knowledge of the true relationship between long-term use of Actos™ and developing bladder cancer, rather than take steps to pull the drug off the market, Defendants promoted Actos™ as a safe and effective treatment for Type II diabetes.

72. Piccinni, et al. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni's results indicated that the reporting odds ratio for pioglitazone was indicative of a "definite risk." Piccinni, et al. Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting, Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

73. Despite their knowledge of this dangerous side effect that can result from Actos™ use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.

74. Actos™ is one of Defendants' top selling drugs. Upon information and belief, in the last year, the medication had global sales of $4.8 billion and accounted for approximately 27% of Takeda's revenue.

75. In 2008, with the knowledge of the risk associated with developing bladder cancer while using Actos™ long term, Takeda Limited achieved its marketing goal by making Actos™ the tenth best-selling medication in the United States all while placing American citizens at risk of developing bladder cancer.

76. Consumers, including Plaintiff, who have used Actos™ for treatment of Type II diabetes, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with long-term Actos™ therapy.

77. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with long-term Actos™ use.

78. As a result of Defendants' actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' conduct.

## IV. NATURE OF THE CASE

79. In or around 2007, Plaintiff MARY SZARKOWSKI was prescribed and began taking Actos™ upon direction of her physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder

cancer in or around February 2017. Plaintiff MARY SZARKOWSKI ceased using Actos™ in or around January 2010.

80. As a direct result of being prescribed Actos™ for many years, Plaintiff MARY SZARKOWSKI has been permanently and severely injured, having suffered serious consequences from long-term Actos™ use.

81. Plaintiff MARY SZARKOWSKI requires and will in the future require ongoing medical care and treatment.

82. Plaintiff MARY SZARKOWSKI, as a direct and proximate result of long-term Actos™ use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living-related expenses due to her new lifestyle.

83. Plaintiff MARY SZARKOWSKI would not have used Actos™ had Defendants properly disclosed the risks associated with its long-term use.

## FIRST CAUSE OF ACTION
## (STRICT PRODUCTS LIABILITY - AS AGAINST THE TAKEDA DEFENDANTS)

84. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

85. At all times relevant hereto, the Takeda Defendants manufactured, designed, distributed, marketed, promoted, and/or sold Actos™.

86. At all times relevant hereto, the dangerous propensities of Actos™ were known to the Takeda Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their

respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

87. The Actos™ prescription drug product as distributed by the Takeda Defendants was defective and unreasonably dangerous, as Takeda failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable and intended use of Actos™ therapy as long-term maintenance for Type II diabetes.

88. Takeda failed to provide an adequate warning to the members of the medical community lawfully authorized to prescribe, dispense, and administer prescription drugs, which includes Plaintiffs' physician.

89. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

**SECOND CAUSE OF ACTION**
**(STRICT PRODUCTS LIABILITY - AS AGAINST THE ELI LILLY DEFENDANTS)**

39. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

40. At all times relevant hereto, the Eli Lilly Defendants marketed, promoted, and/or sold Actos™ throughout the United States.

41. At all times relevant hereto, the dangerous propensities of Actos™ were known to the Eli Lilly Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they marketed, promoted, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients. Eli Lilly was aware or should have been of the concealed risks of Actos, including bladder cancer, but undertook an aggressive marketing campaign which continued to conceal these risks nonetheless.

42. The Actos™ products as marketed, promoted and by Eli Lilly were defective and unreasonably dangerous prescription drug products, as Eli Lilly failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable and intended use of Actos™ therapy as long-term maintenance for Type II diabetes.

43. Eli Lilly failed to provide an adequate warning to the members of the medical community lawfully authorized to prescribe, dispense, and administer prescription drugs, which includes Plaintiffs' physician.

44. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a

personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

## THIRD CAUSE OF ACTION
## (STRICT PRODUCTS LIABILITY – DESIGN DEFECT - AS AGAINST THE TAKEDA DEFENDANTS)

45. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

46. The Takeda Defendants are strictly liable due to the following acts or omissions relating to their failure to properly design the Actos product:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Actos™ without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Actos™ while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Actos™;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Actos™ was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Actos™ was indeed unreasonably unsafe and

unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, the development of bladder cancer;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative Type II diabetic medications available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume Actos™;

g. Advertising, marketing, and recommending the use of Actos™, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Actos™;

h. Representing that Actos™ was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative Type II diabetic medications were available for use for the purpose for which Actos™ was manufactured;

j. Continuing to manufacture and sell Actos™ with the knowledge that Actos™ was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Actos™ so as to avoid the risk of serious harm associated with the use of Actos™;

l. Failing to design and manufacture Actos™ so as to ensure the drug was at least as safe and effective as other Type II diabetic medications;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Actos™ and that use of Actos™ created a high risk of developing bladder cancer;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Actos™.

47. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, bladder cancer and death, as well as other severe and personal injuries as well as physical pain and mental anguish, and diminished enjoyment of life, and financial expenses for hospitalization and medical care.

48. The Takeda Defendants' conduct, as described above, was extreme and outrageous. The Takeda Defendants' risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public regarding the true risks of bladder cancer in Actos user populations.

49. The Takeda Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public of the risks relating to Actos.

50. For these reasons, the Takeda Defendants are strictly liable to Plaintiff's under applicable products liability law without regard to proof of negligence and gross negligence.

51. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

## FOURTH CAUSE OF ACTION
## (FAILURE TO WARN - AS AGAINST THE TAKEDA DEFENDANTS)

52. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

53. The Takeda Defendants are strictly liable for Plaintiff's injuries in the following ways in which they failed to adequately warn of the known dangers of Actos. Specifically, the Takeda defendants:

a. failed to investigate, research, study, and define, fully and adequately, the safety profile of Actos;

b. failed to provide adequate warnings about the true safety risks associated with the use of Actos;

c. failed to provide adequate warning regarding the risk and/or increased risk of bladder cancer in patients using Actos;

d. failed to include a "BOXED WARNING" about the risk and/or increased risk of bladder cancer in patients using Actos;

e. failed to include a "BOLDED WARNNG" the risk and/or increased risk of bladder cancer in patients using Actos

f. Failed to indicate that current, post-FDA approval signal data shows a much high risk for bladder cancer to occur than indicated in clinical studies;

g. Failed to indicate the true level of increased risk of bladder cancer occurrence when using Actos, even with the warning Takeda did provide;

h. Failed to include a "BOXED WARNING" about the risk and/or increased risk of bladder cancer in patients using Actos, even after the 10-year cohort study was completed

i. Failed to communicate to the FDA, Plaintiff, physicians, distributors, pharmacists, and/ or the general public that the use of this drug could cause serious injury and/or death

54. By reason of the foregoing, Takeda has become strictly liable in tort to the Plaintiffs for the marketing, promoting, distribution, and selling of a defective product, Actos, which the Takeda Defendants placed on the market without adequate warnings. The Takeda Defendants breached their duties by failing to provide a reasonably safe pharmaceutical and adequately warn of same. By virtue of the foregoing, the Takeda defendants are jointly and severally liable for Plaintiff's injuries.

55. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using Actos after FDA approval.

56. Even in December 2016 at the end of the 10-year cohort study which determined that Actos can cause bladder cancer, Takeda failed to update its warning to sufficiently reflect the acute risk of bladder cancer when Actos is used.

57. Indeed, throughout the entire lifetime of the Actos product, from 1999 to the current day, the Takeda Defendants failed to update warnings based on information received from product surveillance after Actos was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

58. Takeda failed to do so because it wished to protect one of its most profitable products.

59. Plaintiff used Actos for its approved purpose and in a manner normally intended and reasonably foreseeable by the Takeda Defendants.

60. Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

61. The Takeda Defendants, as the manufacturers and distributors of Actos, are held to the level of knowledge of an expert in the field.

62. The warnings that were given by the Takeda Defendants were not accurate or clear, and further, were false and ambiguous.

63. The warnings that were given by the Takeda Defendants failed to properly warn physicians of the risks associated with Actos, subjecting Plaintiffs to risks that exceeded the benefits to the Plaintiffs. Plaintiffs, individually and through their physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

64. Takeda Defendants had a continuing duty to warn Plaintiffs and their prescriber of the heightened dangers and inaccurate data associated with its product.

65. Takeda Defendants' inadequate warnings of Actos were acts that amount to willful, wanton, and/or reckless conduct by the Takeda Defendants.

66. These aforementioned warning defects in Takeda Defendants' drug Actos were a proximate cause of Plaintiff's injuries.

67. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, bladder cancer and death, as well as other severe and personal injuries as well as physical pain and mental anguish, and diminished enjoyment of life, and financial expenses for hospitalization and medical care.

68. Defendants' conduct, as described above, was extreme and outrageous. Defendant's risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public regarding the true risks of bladder cancer in Actos user populations. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming

public, FDA, physicians, distributors and/or pharmacists.

69. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

## FIFTH CAUSE OF ACTION
## (FAILURE TO WARN - AS AGAINST THE ELI LILLY DEFENDANTS)

70. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

71. The Eli Lilly Defendants are strictly liable for Plaintiff's injuries in the following ways in which they failed to adequately warn of the known dangers of Actos. Specifically, Eli Lilly:

a. failed to investigate, research, study, and define, fully and adequately, the safety profile of Actos;

b. failed to provide adequate warnings about the true safety risks associated with the use of Actos;

c. failed to provide adequate warning regarding the risk and/or increased risk of bladder cancer in patients using Actos;

d. Failed to indicate that current, post-FDA approval signal data shows a much high risk for bladder cancer to occur than indicated in clinical studies in its marketing and promotional materials ;

e. Failed to indicate the true level of increased risk of bladder cancer occurrence when using Actos, even with the warning Takeda did provide in its marketing and promotional materials ;

f. Failed to include a "BOXED WARNING" about the risk and/or increased risk of bladder cancer in patients using Actos, even after the 10 year cohort study was completed;

g. Failed to communicate to the FDA, Plaintiff, physicians, distributors, pharmacists, and/ or the general public that the use of this drug could cause serious injury and/or death

72. By reason of the foregoing, Eli Lilly has become strictly liable in tort to the Plaintiffs for the marketing, promoting, distribution, and selling of a defective product, Actos, which the Eli Lilly Defendants marketed and promoted in concert with Takeda without adequate warnings. The Eli Lilly Defendants breached their duties by failing to provide a reasonably safe pharmaceutical and adequately warn of same. By virtue of the foregoing, the Eli Lilly defendants are jointly and severally liable for Plaintiff's injuries.

73. A manufacturer exercising reasonable care would have updated its warnings based on reports of injuries to individuals using Actos after FDA approval.

74. Indeed, throughout the entire lifetime of the Actos product, the Eli Lilly Defendants failed to update warnings based on information received from product surveillance after Actos was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

75. Eli Lilly failed to update its marketing or promotional materials as well.

76. Eli Lilly failed to do so because it wished to protect one of its most profitable

products.

77. Plaintiff used Actos for its approved purpose and in a manner normally intended and reasonably foreseeable by the Takeda Defendants.

78. Plaintiffs' healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

79. The Takeda Defendants, as the manufacturers and distributors of Actos, are held to the level of knowledge of an expert in the field.

80. The warnings that were given by the Takeda Defendants were not accurate or clear, and further, were false and ambiguous.

81. The warnings that were given by the Defendants failed to properly warn physicians of the risks associated with Actos, subjecting Plaintiffs to risks that exceeded the benefits to the Plaintiffs. Plaintiffs, individually and through their physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

82. Defendants had a continuing duty to warn Plaintiffs and their prescriber of the heightened dangers and inaccurate data associated with its product.

83. Defendants' inadequate warnings of Actos were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

84. These aforementioned warning defects in Defendants' drug Actos were a proximate cause of Plaintiff's injuries.

85. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries as well as physical pain and mental anguish, and

diminished enjoyment of life, and financial expenses for hospitalization and medical care.

86. The Eli Lilly Defendants' conduct, as described above, was extreme and outrageous. Eli Lilly risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public regarding the true risks of bladder cancer in Actos user populations. Eli Lilly made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, FDA, Plaintiff, physicians, distributors, and/or pharmacists.

87. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

## SIXTH CAUSE OF ACTION
## (NEGLIGENCE - AS AGAINST THE TAKEDA DEFENDANTS)

88. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

89. At all times relevant hereto, it was the duty of the Takeda Defendants to use reasonable care in the manufacturing, design, distribution, and/or sale of the aforesaid Actos™.

90. In disregard of its aforesaid duty, the Takeda Defendants were guilty of one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Actos™ without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Actos™ while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Actos™;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Actos™ was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Actos™ was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, the development of bladder cancer;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative Type II diabetic medications available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume Actos™;

g. Advertising, marketing, and recommending the use of Actos™, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Actos™;

h. Representing that Actos™ was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative Type II diabetic

medications were available for use for the purpose for which Actos™ was manufactured;

j. Continuing to manufacture and sell Actos™ with the knowledge that Actos™ was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Actos™ so as to avoid the risk of serious harm associated with the use of Actos™;

l. Failing to design and manufacture Actos™ so as to ensure the drug was at least as safe and effective as other Type II diabetic medications;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Actos™ and that use of Actos™ created a high risk of developing bladder cancer;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Actos™.

o. Failing to communicate to the FDA, Plaintiff, physicians, distributors, pharmacists, and/ or the general public that the use of this drug could cause serious injury and/or death

91. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

**SEVENTH CAUSE OF ACTION**

**(NEGLIGENCE - AS AGAINST THE ELI LILLY DEFENDANTS)**

92. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

93. At all times relevant hereto, it was the duty of the Eli Lilly Defendants to use reasonable care in the manufacturing, design, distribution, and/or sale of the aforesaid Actos™.

94. In disregard of its aforesaid duty, the Eli Lilly Defendants were guilty of one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Actos™ without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Actos™ while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Actos™;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Actos™ was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Actos™ was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, the development of bladder cancer;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative Type II diabetic medications available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions

to those persons to whom it was reasonably foreseeable would prescribe, use, and consume Actos™;

g. Advertising, marketing, and recommending the use of Actos™, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Actos™;

h. Representing that Actos™ was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative Type II diabetic medications were available for use for the purpose for which Actos™ was manufactured;

j. Continuing to manufacture and sell Actos™ with the knowledge that Actos™ was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Actos™ so as to avoid the risk of serious harm associated with the use of Actos™;

l. Failing to design and manufacture Actos™ so as to ensure the drug was at least as safe and effective as other Type II diabetic medications;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Actos™ and that use of Actos™ created a high risk of developing bladder cancer;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Actos™.

o. Failing to communicate to the FDA, Plaintiff, physicians, distributors, pharmacists, and/ or the general public that the use of this drug could cause serious injury and/or death

95. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a

personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

## EIGHTH CAUSE OF ACTION
## (BREACH OF EXPRESS WARRANTY - AS AGAINST THE TAKEDA DEFENDANTS)

96. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

97. The Takeda defendants expressly warranted that Actos was safe and well accepted by users.

98. Actos does not conform to these express representations because Actos is not safe and has numerous serious side effects, many of which were not accurately warned about by the Takeda defendants.

99. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

100. Plaintiff did rely on the express warranties of the Takeda defendants herein.

101. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Actos in recommending, prescribing and dispensing Actos.

102. The Takeda defendants herein breached the aforesaid express warranties, as their drug Actos was defective.

103. Takeda defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and the FDA that Actos was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing and controlling the blood sugar of patients with type II diabetes.

104. Takeda defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Actos was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Takeda defendants.

105. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

**NINTH CAUSE OF ACTION**
**(BREACH OF EXPRESS WARRANTY - AS AGAINST THE ELI LILLY DEFENDANTS)**

106. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

107. The Eli Lilly defendants expressly warranted that Actos was safe and well accepted by users, particularly during their marketing and promotional campaign for the Actos drug.

108. Actos does not conform to these express representations because Actos is not safe and has numerous serious side effects, many of which were not accurately warned about by the Takeda defendants.

109. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

110. Plaintiff and her physicians did rely on the express warranties of the Eli Lilly defendants herein.

111. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Eli Lilly defendants for use of Actos in recommending, prescribing and dispensing Actos.

112. The Eli Lilly defendants herein breached the aforesaid express warranties, as their drug Actos was defective.

113. Eli Lilly defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and the FDA that Actos was safe and fit for use for the purposes intended,

that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing and controlling the blood sugar of patients with type II diabetes.

114. Eli Lilly defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Actos was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Takeda defendants.

115. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

## TENTH CAUSE OF ACTION
## (BREACH OF IMPLIED WARRANTIES - AS AGAINST THE TAKEDA DEFENDANTS)

116. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

117. At all times herein mentioned, the Takeda Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and have recently acquired the Takeda Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos to reduce and control blood sugar in type II diabetic patients.

118. At the time Takeda Defendants marketed, sold and distributed Actos for use by Plaintiff, the Takeda Defendants knew of the use for which Actos was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

119. The Takeda Defendants impliedly represented and warranted to the users of Actos and their physicians, healthcare providers, and the FDA that Actos was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

120. That said representations and warranties aforementioned were false, misleading and inaccurate in that Actos was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

121. Plaintiff and members of the medical community and healthcare professions did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

122. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Actos was of merchantable quality and safe and fit for its intended use.

123. Actos was placed into the stream of commerce by the Takeda Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

124. The Takeda Defendants herein breached the aforesaid implied warranties, as their drug Actos was not fit for its intended purposes and uses.

125. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

## ELEVENTH CAUSE OF ACTION
## (BREACH OF IMPLIED WARRANTIES - AS AGAINST THE ELI LILY DEFENDANTS)

126. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

127. At all times herein mentioned, the Eli Lilly Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and have recently acquired the Eli Lilly Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos to reduce and control blood sugar in type II diabetic patients.

128. At the time Eli Lilly Defendants marketed, sold and distributed Actos for use by Plaintiff, Eli Lilly Defendants knew of the use for which Actos was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

129. The Eli Lilly Defendants impliedly represented and warranted to the users of Actos and their physicians, healthcare providers, and the FDA that Actos was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

130. Eli Lilly sent employees and agents to market and promote the Actos product, despite its knowledge of the risk of bladder cancer relating to Actos.

131. That said representations and warranties aforementioned were false, misleading and inaccurate in that Actos was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

132. Plaintiff and members of the medical community and healthcare professions did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

133. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Actos was of merchantable quality and safe and fit for its intended use.

134. Actos was placed into the stream of commerce by the Eli Lilly Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

135. The Eli Lilly Defendants herein breached the aforesaid implied warranties, as their drug Actos was not fit for its intended purposes and uses.

136. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

## TWELFTH CAUSE OF ACTION
## (NEGLIGENCE *PER SE* - AS AGAINST THE TAKEDA DEFENDANTS)

137. Plaintiff incorporates and reasserts the allegations above as if fully set forth herein.

138. As part of their duty to exercise reasonable care for the safety of persons, including Plaintiff, who would be expected to use their products, the Takeda defendants were obliged to follow public laws and regulations enacted and promulgated to protect the safety of such persons, including 21 U.S.C. 331(a) and 352, and other statutes and regulations, which make it unlawful to misbrand prescription drug products.

139. The package inserts (and other labeling, if any) for each of the Actos products failed to conform to the requirements of 21 U.S.C. §352, including subsections (a), (c), and (f), or the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a),

as the package inserts and/or other labeling failed to contain, *inter alia*, information, including warnings and instructions for use, adequate to enable the use of Actos in an ordinary, foreseeable, and intended manner that was reasonably safe, taking into account the potential benefits and potential risks entailed in such use, or to bear "information for its use, including... any relevant hazards, contraindications, side effects, and precautions" that were adequate to enable doctors to "use the drug safely and for the purposes for which it is intended"; and, in addition, contained false, inaccurate, and/or misleading statements concerning their respective products' side effects.

140. With respect to the prescription drug Actos, the Takeda defendants, have or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a) The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b) The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for ACTOS and such deviations are not plainly stated on their labels.

c) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false or misleading.

d) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the

labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g) The prescription drug Actos does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

h) The Takeda defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i) The prescription drug Actos is misbranded pursuant to 21 CFR §201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j) The Takeda defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Actos' cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k) The Takeda defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.

l) The Takeda defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

m) The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

n) The Takeda defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class.

o) The Takeda defendants violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendants failed to list the development of Cardiac Arrhythmia before the other adverse reactions on the labeling of the prescription drug Actos.

p) The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate an upper limit beyond which safety and effectiveness have not been established.

q) The prescription drug Actos violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety, have the identity and strength, and meets the quality and purity characteristic that they purport or are represented to possess.

r) The prescription drug Actos violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

s) The prescription drug Actos violates 21 CFR §211.165 because the test methods employed by the Takeda defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

t) The prescription drug Actos violates 21 CFR § 211.165 in that the prescription drug ACTOS fails to meet established standards or specifications and any other relevant quality control criteria.

u) The prescription drug Actos violates 21 CFR §211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed.

v) The prescription drug Actos violates 21 CFR § 310.303 in that the prescription drug Actos is not safe and effective for its intended use.

w) The Takeda defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

x) The Takeda defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

y) The Takeda defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event.

z) The Takeda defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

aa) The Takeda defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

bb) The Takeda defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up."

cc) The Takeda defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

dd) The Takeda defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ee) The Takeda defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

141. Accordingly, the Takeda defendants, in distributing the Actos products labeled in violation of these statutes and associated regulations, were negligent *per se*, that is, negligent as a matter of law.

142. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiffs have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

**WHEREFORE,** Plaintiffs hereby demand a trial by jury and judgment against the Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

**WHEREFORE**, Plaintiffs demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiffs for the injuries Plaintiffs have and will suffer. Plaintiffs further demand judgment against each of the Defendants for punitive damages. Plaintiffs further demand payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiffs further demand payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

Dated: June 20, 2019

MARY SZARKOWSKI,

By their attorneys:

By: /s/ Nicholas B. Carter

Nicholas B. Carter, Esq.
**TODD & WELD LLP**
One Federal Street, 27th Floor
Boston, MA 02110
(617) 720-2626
ncarter@toddweld.com

Nicholas R. Farnolo (*pro hac vice* to be applied for)
Hunter J. Shkolnik (*pro hac vice* to be applied for)
**NAPOLI SHKOLNIK, PLLC**
400 Broadhollow Road
Suite 305
Melville, NY 11747

(212) 397-1000
Hunter@napolilaw.com
Nfarnolo@napolilaw.com
*Attorneys for Plaintiff*